

REMARKS/ARGUMENTS

This letter is responsive to the Office Action dated **January 21, 2004**.

Claim Amendments

Applicant has amended Claims 1, 7 and 20 to clarify the structure of the invention. No new subject matter has been added to the claims and a new search is not necessary.

Anticipation Under 35 USC 102(b) & (e)

The Examiner rejected Claims 1-3, 5, 6-7 and 20 rejected under 35 U.S.C. 102(b) as being anticipated by Wilburn (US Patent No. 2,860,635). The Examiner also rejected Claims 1-2, 7-10 and 20 under 35 U.S.C. 102(b) as being anticipated by Helixon (US Patent No. 4,091,812). The Examiner still further rejected claims 1, 5-7 and 20 under 35 U.S.C. 102(e) as being anticipated by Peterson et al (US Patent No. 6,156,014).

Reconsideration thereof is requested in light of Applicant's amendments and the following arguments.

The structure as claimed in independent claims 1 and 20 is different from the structure set forth in Wilburn. Claims 1 and 20 very clearly recite a body having a "rimmed end" 24 as illustrated in Fig. 2. It is this rimmed end which engages an inwardly projecting portion 48 (Figs. 1 and 2) so as to position the body intermediate the top end and the base end of the sleeve. Applicant's invention positions the body intermediate the top end and the base end of the sleeve so that a **longitudinal gap** is created between the upper surface of the

piston and the rimmed end of the body enabling better sterilization of the assembly.

Wilburn and Helixon do not have bodies with rimmed ends. The pistons in Wilburn, Helixon and Peterson et al are located in the syringe body. **The piston in the instant invention is recited in independent claims 1 and 20 as residing outside the syringe body.**

Wilburn inserts its piston up inside the body creating a geometrical orientation of the parts which is more difficult to sterilize. In other words, a narrow annular gap is formed between the piston and the body in Wilburn which is difficult to sterilize. Specifically, claim 1 of applicants invention recites, in pertinent part, the “upper surface of said piston distally located with respect to said piston support means, said upper surface of ***said piston being spaced longitudinally apart from the rimmed end*** “. Applicant’s invention longitudinally spaces the piston apart from the rimmed end of the body. In this way the rubber component, the piston, is kept away from the glass. Further, in the event that the piston is unintentionally diametrically oversized, applicant’s invention permits the safe sterilization of the piston whereas in Wilburn if the diameter of the piston is too large, the piston would engage the wall of the body of the syringe.

Similarly, Helixon’s body 12 does not have a rimmed end. Rather, Helixon’s body appears to be completely cylindrical. Helixon’s invention is not directed to sterilization and therefore there is no need to position the body intermediate the top end and the base end of the sleeve.

In regard to Peterson et al, the Examiner argues that Peterson discloses a body 1 with a rimmed end 15. However, even if rimmed end 15 is read to constitute the claimed rimmed end, it is not longitudinally spaced above the piston 8. Piston 8 is jammed up inside body 1 with medicament secured therein. Claim 1 as amended recites that the upper surface of the piston is distally located with respect to the piston support means and the lower surface of the piston is proximate to and engages the piston support means. The upper surface of piston 8 of Helixon resides near penetrator 11 and there is no longitudinal gap between the piston and the rimmed end. Further, the piston does not engage the piston support means. It is obvious that Peterson et al. is not directed toward sterilization. In that Peterson is missing several elements as claimed in claims 1 and 20, reconsideration of claims 1, 5-7 and 20 is requested.

It is respectfully submitted, that to reject a claim under 35 U.S.C. 102(b), the office must demonstrate that each and every claim limitation is *identically* disclosed in a single prior art reference. Anticipation is a question of fact. There must be no difference between the claimed invention and the reference's disclosure as viewed by a person of ordinary skill in the field of the invention. *Scripps Clinic & Research Foundation v. Genentech, Inc.*, 18 USPQ2d 1001 (Fed. Cir. 1991) citing *Shatterproof Glass Corp. v. Libbey-Owens Ford Co.*, 758 F.2d 613, 619, 225 USPQ 634, 637 (Fed. Cir.), *cert. dismissed*, 474 U.S. 976 (1985). Here, the differences between the claimed invention as set forth in claims 1 and 20 and the references are significant and a rejection under 35 U.S.C. §102(b) is not proper. Dependent

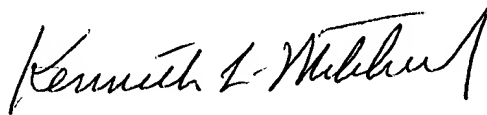
claims 2, 3, and 5-7 are directly or indirectly dependent on claim 1. As such, Wilburn, Helixon and Peterson et al do not anticipate claims 1-3, 5-7 and 20 and it is respectfully submitted that the Examiner reconsider the rejection of those claims.

The prior art does not render any of the claims obvious.

Applicant wishes to thank the Examiner for the interviews on February 13, 2004, February 16, 2004 and March 31, 2004 for her careful review of this application.

Applicants respectfully request that the withdrawn claims be rejoined.

Respectfully submitted,

A handwritten signature in black ink, appearing to read "Kenneth L. Mitchell". The signature is fluid and cursive, with a large, sweeping final stroke.

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